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## **Australia**

### **Biotechnology - GE Plants and Animals**

#### **Agricultural Biotechnology Report 2010**

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**Report Highlights:**

The moratoria on planting of canola varieties which were in place for a number of years after GM canola was approved for commercial release in Australia were lifted in 2008 in NSW and Victoria and the first commercial plantings of canola took place that year. Western Australia lifted its moratoria on GM crops in November 2008 to allow GM cotton to be grown in the Ord River region and in April 2009 allowed trials of GM canola. In early 2010, WA passed legislation to allow commercial plantings of canola. This has led to a more than trebling in area planted to GM canola in Australia in 2010 to 133,330 hectares, representing 8.3 percent of the total Australian canola crop. The moratoria remain in place in South Australia, Tasmania and the ACT.

## Section I. Executive Summary:

The United States has substantial interest in Australia's policies and regulatory framework regarding agricultural biotechnology and products derived thereof because of the impact this has on the ability of the U.S. to export to Australia. Unprocessed (whole) biotech corn and soybeans have not received regulatory approval in Australia and, thus, cannot be imported without further processing. Foods with biotech content of over 1 percent must receive prior approval and be labeled. This requirement can restrict sales of U.S. intermediate and processed products. Australia's policies and views on this technology influence other countries in the region, and elsewhere, which may follow Australia's lead in developing a regulatory system of their own.

The biotech debate is very important in Australia. The federal government is very supportive of the technology, has committed considerable long-term funding to research and development, and has approved genetically modified (GM) canola varieties for general release. The State governments have also committed funds for research and development, but most were more cautious about the introduction of the technology and most Australian states initially put in place moratoria on new plantings of biotechnology crops. After state-level reviews in November 2007, New South Wales and Victoria lifted the moratoria on genetically engineered canola. In November 2008, Western Australia lifted its ban to allow biotech cotton to be grown in the Ord River region and in April 2009 announced that trials of GM canola would be allowed. In early 2010, WA passes legislation allowing the commercial production of GM canola in that state. Plantings of GM varieties in the three states allowing GM canola production are estimated at 133,330 hectares which is 8.3 percent of the total Australian crop. South Australia, Tasmania and the Australian Capital Territory (ACT) have maintained their moratoria. Major farm groups and the Commonwealth government's science organizations do not support this position and have argued openly for acceptance of biotech crops. Currently in Australia, about 95 percent of the cotton planted is from biotech varieties, which were approved for release prior to the state moratoria. Although GM cotton varieties dominate the cotton industry in Australia, the state moratoria slowed the commercialization and adoption of the technology for food crops.

Australia has a substantial risk assessment based regulatory framework for dealings with gene technology and genetically modified organisms, as well as a process for assessment and approval of genetically modified foods. The Gene Technology Act of 2000 established Australia's regulatory scheme for dealings with gene technology and genetically modified organisms (GMOs). The Commonwealth's Gene Technology Regulator serves the key role in assessing, regulating and licensing GMOs and enforcing license conditions. Genetically modified foods must also be assessed, determined to be safe, and be approved before being sold for human consumption. The standards for such foods are developed by Food Standards Australia New Zealand (FSANZ) and are contained in the Food Standards Code. There are labeling requirements for genetically modified foods containing modified genetic material and/or novel protein, and for foods with altered characteristics. Imports of viable GMOs and food products containing genetically modified ingredients need to meet these same regulations.

To date, biotech cotton, canola and rose varieties are the only agricultural crops approved for commercial release into the environment in Australia. A full list of the various varieties and traits approved for commercial release can be found on the OGTR website at the bottom of [this page](#). With the lifting of the moratoria in New South Wales, Victoria and Western Australia, plantings of GM canola are expected to continue to increase rapidly. Research is being conducted on other biotech crops, with field trials controlled by the OGTR being conducted on some, e.g. Indian mustard, wheat, sugarcane, white clover, grapevines, pineapple, papaya, canola and cotton (see Appendix II). Approval has already been granted for food products derived from biotech corn, cotton, soybean, sugar beet, potatoes, alfalfa and rice (see Appendix III).

For GMOs that have not received regulatory approval in Australia, U.S. export opportunities are obviously restricted. For the United States, the commercial impact of this constraint is most pronounced for feed grains, e.g. whole corn, and soybeans as these products have not yet received regulatory approval. In addition to this market access restriction, Australia does not allow the importation of many grains and/or grain products for phytosanitary reasons, citing the need to limit exotic weed seeds.

Australia requires that food products derived from GMOs, if they contain more than one percent of biotech product, get prior approval from Food Standards Australia New Zealand before they can be sold. Such products must also be labeled to indicate that they contain biotech products.

## **SECTION II: PLANT BIOTECHNOLOGY TRADE AND PRODUCTION**

### **Commercial Crops**

Biotech cotton, canola and roses are the only crops approved for commercial release by Australia's Gene Technology Regulator. It is estimated that biotech cotton varieties are grown on up to 95 percent of Australia's cotton area. The Regulator approved the commercial releases of two biotech canola varieties in 2003. With the lifting of the moratoria in New South Wales and Victoria in early 2008, that was the first year that GM canola was grown commercially anywhere in the country. In November 2008, Western Australia lifted its ban to allow biotech cotton to be grown in the Ord River region and in April 2009 announced that trials of GM canola would be allowed at 20 sites in that state.

Biotech carnations became the first biotech products to be assessed by the Gene Technology Regulator to "pose minimal risks to people or the environment, and are sufficiently safe to be used by anyone without the need for a license" and they have accordingly been placed on the GMO Register.

#### Biotech Cotton

Biotech cotton has been grown commercially in Australia since the approval and introduction of the first GM variety in 1996. Currently, around 95 percent of the Australian cotton crop is made up of GM varieties. In addition, there are a number of new biotech cotton varieties currently being developed (see Appendix II at the end of this report).

Australian food standards require approval and labeling of food or food ingredients that contain new genetic material or protein or have altered characteristics as a result of gene modification. Refined oil from biotech cottonseed, however, does not require a label because the oil contains no genetic material and the cottonseed oil is identical to conventional cottonseed oil.

#### Canola

Since 2003 a number of biotech canola varieties have been approved by OGTR. The first commercial plantings of these varieties took place in 2008 after the state governments in NSW and Victoria lifted their moratoria on commercial plantings of GM canola and in 2009 Western Australia also allowed trials to begin. In 2010, just the third year of commercial availability in NSW and Victoria and the first year of commercial production in Western Australia, it is estimated that farmers have planted a total area of approximately 133,330 hectares of Roundup Ready canola varieties - 8.3 percent of total area planted to all canola varieties in Australia. This is more than three times the total area planted in 2009, with a huge uptake of the technology in Western Australia. Plantings per state in 2010 have been: 72,790 ha in Western Australia; 24,040 ha in NSW; and, 36,500 ha in Victoria (these areas are subject to change as seasonal conditions develop). If rainfall and seasonal conditions remain 'average' through to harvest, the yield of GM canola crops is forecast at 160,000 MT. The total Australian canola crop is for this year is forecast at 1.960 million MT.

### **Applications Under Evaluation**

A list of GMO applications currently under evaluation by OGTR is contained in Appendix I of this report.

### **Imported Products**

Under the Gene Technology Act 2000, approval or authorization must be obtained to deal with genetically modified organisms. This means that the importation of live, viable GMOs, are regulated under the Act. Importers need to apply to OGTR for a license or authorization to import any GMO into Australia. OGTR and the Australian Quarantine and Inspection Service (AQIS) work closely to regulate and enforce this situation. The AQIS application form for an import permit contains a section relating to the genetically modified status of the product.

Foods containing biotech materials must be approved by Food Standards Australia New Zealand and be labeled if the biotech content is greater than 1% before they can be sold in Australia. This applies to all domestically produced and imported food. A list of currently approved biotech food products is contained in Appendix III of this report.

Processed animal feeds, such as soy meal, are not covered by biotech legislation in Australia. These products, therefore, do not require prior approval or a license (see Section III of this report) to be imported. There are, however, quarantine restrictions on some products. Unprocessed biotech products imported as feed (i.e. whole grain, etc), would require a license from OGTR, as there is a possibility that seed could be released into the environment.

### **Products Developed Outside U.S.**

GM crops grown in Australia have been developed in Australia (see Appendices I & II for list of crops & their developers). Given that most of Australia's cotton products come from GM varieties, it is likely that any exports of cotton & cotton products would contain these varieties. Australia does not export cotton to the U.S. but in 2009, Australia exported 22.5 MT of cotton seed to the U.S. (tariff code 1207.20). There is no way of knowing for certain whether this seed was from GM or non-GM varieties.

## **SECTION III: PLANT BIOTECHNOLOGY POLICY**

### **The GMO Regulatory System**

The Gene Technology Act 2000 (the Act) came into force on June 21, 2001 as the Commonwealth component of a national regulatory scheme. The Act and the associated Gene Technology Regulations 2001, provide a comprehensive process for the Gene Technology Regulator to assess proposed dealings with live and viable GMOs ranging from contained work in certified laboratories to general releases of GMOs into the environment, and extensive powers to monitor and enforce license conditions. An Inter-Governmental Agreement, between the Commonwealth and the states and territories, underpins the system for regulating genetically modified organisms in Australia. The Ministerial Council for Gene Technology, comprising ministers from the Commonwealth and each state and territory, oversees the regulatory framework and provides advice to the Gene Technology Regulator on policy principles to assist in decision-making. The individual states and territories have passed or are developing complimentary legislation to the Gene Technology Act in their jurisdictions.

The object of the Gene Technology Act is: "To protect the health and safety of people, and to protect the environment, by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with genetically modified organisms."

The Act prohibits all dealings with GMOs unless the dealing is:

- A licensed dealing;
- A notifiable low risk dealing;
- Exempt dealing; or
- Included on the GMO Register.

Key features of the Act are the appointment of an independent Gene Technology Regulator and a requirement for transparent and accountable implementation. The Regulator administers the regulation of all dealings with GMOs in Australia, in accordance with the Act and ensures compliance with the conditions of any approvals. The Regulator consults extensively with the community, research institutions and private enterprise.

The Gene Technology Regulator liaises with other regulatory agencies to coordinate the approval of biotech products for use and sale (see table below). The Act creates a Public Record of GMO Dealings and GM Products that resides on the OGTR website: [www.ogtr.gov.au](http://www.ogtr.gov.au).

## Regulatory Agencies in Australia with a Role in Regulation of Gene Technology

Agency	What They Regulate	Scope	Relevant Legislation
<b>OGTR</b> – Office of the Gene Technology Regulatory (supporting the Gene Technology Regulator)	Dealings with GMOs	The Gene Technology Regulator administers a national scheme for the regulation of GMOs in Australia in order to protect health & safety of people, and to protect the environment, by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with GMOs.	Gene Technology Act 2000
<b>TGA</b> – Therapeutic Goods Administration	Medicines, medical devices, blood & tissues	TGA administers legislation that provides a national framework for the regulation of medicines, medical devices, blood and tissues in Australia, including GM & GM-derived therapeutic products, & ensures their quality, safety & efficacy.	Therapeutic Goods Act 1989
<b>FSANZ</b> – Food Standards Australia & New Zealand	Food	FSANZ is responsible for setting standards for the safety, content and labeling of food. FSANZ conducts mandatory pre-market safety assessments for food produced using gene technology.	Food Standards Australia New Zealand Act 1991
<b>APVMA</b> – Australian Pesticides & Veterinary Medicines Authority	Agricultural & Veterinary Chemicals	APVMA operates the national system that regulates all agricultural chemicals (including those produced or used on GM crops) and veterinary therapeutic products. Assessments consider human and environmental safety, product efficacy (including insecticide and herbicide resistance management), and trade issues relating to residues	Agricultural & Veterinary Chemicals (Code) Act 1994  Agricultural & Veterinary Chemicals Administration Act 1994
<b>NICNAS</b> – National Industrial Chemicals Notification & Assessment Scheme	Industrial Chemicals	NICNAS provides a national notification & assessment scheme to protect the health of the public, workers & the environment from the harmful effects of industrial chemicals.	Industrial Chemicals (Notification & Assessment) Act 1989
<b>AQIS</b> – Australian Quarantine & Inspection Service	Quarantine	AQIS regulates the importation into Australia of all animal, plant & biological products that may pose a quarantine pest &/or disease risk. Import permit applications must indicate the presence of GMOs or GM material and the relevant authorization under the Gene Technology Act 2000.	Quarantine Act 1908  Imported Food Control Act 1992

The Act also establishes three committees to advise the Regulator and the Ministerial Council:

- The Gene Technology Technical Advisory Committee (GTTAC) – a group of highly qualified experts who provide scientific and technical advice on applications;
- The Gene Technology Ethics Committee (GTEC) – a group of expert ethicists, which provides ethical advice, particularly in the areas of law, religious practices, animal welfare and population health; and
- The Gene Technology Community Consultative Committee (GTCCC) – a group of people representing the broad interests within the Australian community, including consumers, researchers, and environmentalists. This group looks beyond the science of gene technology to matters of general concern to the community in relation to GMOs.

## **GMOs vs GM Product**

The Gene Technology Act 2000 distinguishes between genetically modified organisms (GMOs) and genetically modified (GM) products. A genetically modified product - 'GM product' - means a thing (other than a GMO) derived or produced from a GMO (Section 10 of the GT Act).

The Office of the Gene Technology Regulator (OGTR) does not directly regulate the use of GM products in Australia. However, the use of GM products is regulated by other regulatory agencies in a number of situations as set out in the table above.

## **GMOs Already Licensed by OGTR**

A list of GMOs already licensed by OGTR is contained in Appendix II of this report.

## **Biotech Food**

Food Standards Australia New Zealand (FSANZ) is the Australian Government agency responsible for approving GM food products for the Australian market. Mandatory labeling of genetically modified foods, where introduced DNA or protein is present in the final food, came into force in Australia on December 7, 2001. Regulations for labeling are contained in [Standard 1.5.2](#) of the [Food Standards Code](#). A list of currently approved biotech food products is contained in Appendix III of this report.

Under the Standard, food or ingredients labeled genetically modified contain new genetic material or protein as a result of the genetic modification or have altered characteristics, e.g. changed nutritional values, compared to the conventional food. Some flavorings may also be derived from genetically modified organisms, but labeling is only required if they are in a concentration of more than 1 gram per kilogram (0.1%). Food additives and processing aids do not need to be labeled unless the introduced genetic material is present in the final food.

Under the labeling standard, for packaged foods the words 'genetically modified' must be used in conjunction with the name of the food, or in association with the specific ingredient within the ingredient list; and for unpackaged foods for retail sale (such as unpackaged fruit and vegetables, or unpackaged processed or semi-processed foods) the words 'genetically modified' must be displayed in association with the food, or in association with the particular ingredient within that food.

## **Biotech Feed Products**

Animal feeds containing GMOs (e.g. whole grains or oilseeds) are regulated by the OGTR. The OGTR considers any biosafety risks associated with the product and, if necessary, will apply special conditions, or may prohibit the use of the product as animal feed. As an example, after a GMO has undergone field trials, the organization conducting the trials may wish to use the unviable by-product (such as seed) as animal feed. Before the product is used in any way, the Gene Technology Regulator will consider any risks and, if necessary, will apply conditions or disallow the product to be used.

The Australian Quarantine & Inspection Service (AQIS) and the OGTR must approve genetically modified whole grain commodities (including oilseeds) imported into Australia for animal feed (such as whole soybeans and corn). The AQIS provides quarantine inspection and certification for the arrival of imports of the products to ensure the product is free of pest and disease and specific license conditions are enforced to ensure the product meets requirements. The OGTR also assesses the product, issues a license to the organization importing the product, and may apply further conditions above those stipulated by AQIS.

Large amounts of biotech feed products are used in Australia's intensive livestock sector. A large proportion of Australia's soybean meal is imported, including from the United States. All cottonseed meal used in Australia is considered to be biotech as over 90 percent of the cotton crop is planted to biotech varieties. Biotech and non-biotech cotton varieties are not typically segregated in Australia.

Genetically modified animal feed does not require special labeling in Australia.

### **Coexistence between Biotech & Non-Biotech Crops**

Coexistence of biotech, conventional, and organic crops has occurred in Australia since biotech cotton varieties were commercially grown in 1996. As part of any license to grow a biotech crop, OGTR stipulates the conditions under which the crop can be grown to ensure no cross-contamination with conventional or organic crops in the vicinity.

In October 2005, national consensus was achieved in Australia regarding practical thresholds to deal with the issue of traces of GM canola in conventional canola consignments and variety trials. The Primary Industries Ministerial Council (PIMC), which is comprised of Ministers from the Australian Government and each state and territory, agreed upon adventitious presence (AP) thresholds for the presence of GM canola in conventional grain and seed.

The PIMC meeting agreed on two thresholds:

- An AP threshold of 0.9 per cent GM canola in canola grain. This is the threshold supported by the Australian Oilseeds Federation (AOF).
- A second threshold for AP of GM canola in seed was set at 0.5 per cent for 2006 and 2007, to be reduced to 0.1 per cent thereafter. The Australian Seed Federation (ASF) established an AP threshold of 0.5 per cent GM seed in non-GM planting seed in 2003 following two years of research and consultation with the canola seed industry.

A number of projects on GMO supply chain management have been undertaken as part of the Department of Agriculture, Fisheries & Forestry's Biotechnology Strategy for Agriculture, Food and Fibre (BSAFF). These publications are available at: <http://www.daff.gov.au/agriculture-food/biotechnology>.

### **Biosafety Protocol**

Australia has not signed or ratified the Biosafety Protocol and the Australian Government has no timetable for consideration of accession to the Protocol. This was due to concerns about how the Protocol will operate in practice (documentation requirements, and the liability and compliance arrangements are yet to be agreed), uncertainty about how parties will implement the Protocol and whether they will do so in a way which respects all of their international obligations, and uncertainty about any individual country's capacity to influence decision-making. The Australian government considers that the Protocol is not needed for Australia to manage biotech imports as Australia already has a robust regulatory framework through the Office of Gene Technology Regulator.



## SECTION IV: PLANT BIOTECHNOLOGY MARKETING ISSUES

### Market Acceptance

Australia has a substantial, risk assessment based regulatory framework for dealings with gene technology and genetically modified organisms and the Government is supportive of the technology for its agricultural producers and has been an ally of the United States with regard to the Cartagena Protocol on Biosafety (CPB). This comes despite anti-biotechnology activism in Australia that promoted stringent labeling requirements and encouraged moratoria on biotechnology plantings. Australia's biotechnology sector is small in global terms, but growing, with over 440 biotechnology companies (this includes all types of biotechnology, not just agricultural biotechnology).

Major Australian commodity groups originally voiced concerns about introducing biotech canola and advocated for a 'go-slow' approach largely because of the potential impact biotech canola, which OGTR approved for commercial release in 2003, could have on their domestic and export businesses. In 2003 and 2004, several state governments (Victoria, NSW, South Australia, Western Australia, Tasmania and the ACT), using their powers over commodity 'marketing', imposed moratoria on the commercial release of products of biotechnology (with the exception of the previously approved cotton and carnations). Most of the moratoria were reviewed in 2007, and the states of NSW and Victoria lifted their bans on commercial plantings of GM canola and the first commercial crops were grown in these two states in 2008. In November 2008, the Western Australian government lifted their moratoria to allow GM cotton to be grown in the Ord River area and in April 2009 they also announced that trials of GM canola would be allowed at 20 sites in that state. Moratoria remain in place in South Australia, Tasmania and the ACT.

Currently in Australia about 95 percent of the cotton planted is from biotech varieties, and there has been little controversy concerning its cultivation. Indeed, environmental benefits and the significant decline in pesticide and herbicide use for this crop have been widely reported. Biotech cottonseed does appear in the domestic market through the oil and meal, and this has not met with any major opposition.

A survey conducted on behalf of Biotechnology Australia in 2007 comparing changes in consumer attitudes towards biotechnology from 2005 to 2007 found significant increases in both awareness of and support for GM food crops since 2005. Attitudes towards biotechnology in food and agriculture were found to be, on balance, less positive than attitudes towards biotechnology in health and medicine. Many respondents tended to associate GM crops with commercial objectives – although when prompted (and sometimes spontaneously), people voiced strong support for the development of GM crops that could contribute to humanitarian or environmental objectives (the most prominent example being drought resistant crops). Most participants in the survey regarded environmental objectives as very valuable in the development of gene technology and GM plants.

The survey found that, broadly speaking, it appears that people became more familiar with biotechnology and gene technology between 2005 and 2007 and that there was no reason to suppose that the trend towards greater acceptance would not continue, as these technologies become a more normal part of everyday life. They found that there was no great public appetite for detailed factual information about how things are done; rather, people were more interested in learning about the potential benefits of technology.

Biotechnology Australia ceased operations in 2008 and no followup survey has been conducted since. A full copy of the 2007 survey report is available at:

<http://www.biotechnology.gov.au/assets/documents/bainternet/Eurekafoodandagriculture200720070801082636.pdf>

A number of reports on market acceptance are also available on the DAFF website at: [http://www.daff.gov.au/agriculture-food/biotechnology/reports/marketing\\_and\\_trade](http://www.daff.gov.au/agriculture-food/biotechnology/reports/marketing_and_trade).

## **Country Specific Studies Relevant to U.S. Exporters**

The **Department of Agriculture, Fisheries & Forestry** has a number of publications, studies and fact sheets available on the [Agriculture & Food Biotechnology page](#).

[\*\*Agrifood Awareness Australia\*\*](#) – This organization publishes a large number of bulletins and information guides.

The [\*\*Australian Bureau of Agriculture & Resource Economics \(ABARE\)\*\*](#) has released a large number of studies & papers on GM industries. Conduct a search for GM on the ABARE website.

In September 2007, the **National Farmers Federation** released a [Gene Technology Policy](#) recognizing the potential of biotechnology as a valuable tool within agricultural production systems and urging that all potential benefits should be available to farmers to make informed choice in their farming decisions.

## **SECTION V: ANIMAL BIOTECHNOLOGY**

There is a small amount of work currently being conducted in Australia on genetically engineered agriculturally-relevant animals – mainly chicken & sheep. The work is in the very early stages and is being carried out by public and private research institutions and universities. GE animals are considered ‘Notifiable Low Risk Dealings’ (NLRDs) by the OGTR – i.e. “dealings with GMOs that have been assessed as posing low risk to the health and safety of people and the environment provided certain risk management conditions are met.” A full list of NLRDs, including the institutions carrying out the research, is available on the OGTR website at: <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/nlrclass-2>.

No GE animals are currently anywhere near the commercial production stage.

## **SECTION VI: REFERENCE MATERIAL**

Below are links to various organizations involved in the agricultural biotechnology sector in Australia.

### Australian Government

[Office of the Gene Technology Regulator](#)

[Food Standards Australia New Zealand](#)

[Australian Pesticides & Veterinary Medicines Authority](#)

[Department of Agriculture, Fisheries & Forestry](#)

[Department of Innovation, Industry, Science & Research](#)

[Commonwealth Scientific & Industrial Research Organization \(CSIRO\)](#)

### Other Organizations

[Agrifood Awareness Australia](#)

[National Farmers Federation](#)

## APPENDIX I: GMO APPLICATIONS UNDER EVALUATION

The Office of the Gene Technology Register has received the following applications for evaluation. All applications are posted on the OGTR website when they are first received and again when public comment is sought. Full details of all applications can be found at: <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/ir-evaluation-1>

Product	Trait Category	Applicant	Status
<b>Canola &amp; Indian Mustard</b>	Limited and controlled release of canola and Indian mustard genetically modified for herbicide tolerance and/or a hybrid breeding system	Bayer CropScience Pty Ltd	Notification posted May 7, 2010
<b>Canola</b>	Limited and controlled release of canola genetically modified for enhanced yield and delayed leaf senescence	Victorian Department of Primary Industries	Notification posted February 22, 2010
<b>Cotton</b>	Limited and controlled release of cotton genetically modified for insect resistance and herbicide tolerance	Monsanto Australia Limited	Notification posted February 8, 2010
<b>Wheat &amp; Barley</b>	Limited and controlled release of wheat and barley genetically modified for abiotic stress tolerance	University of Adelaide	Notification posted January 22, 2010
<b>Vaccine</b>	Commercial release of a genetically modified live viral vaccine to protect against Japanese encephalities (IMOJEV™)	Sanofi Pasteur Pty Ltd	Notification posted October 29, 2009

## APPENDIX II: GMOs ALREADY LICENSED FOR USE IN AUSTRALIA

The table below provides summary information about all current Dealings for Intentional Release (DIRs) on the GMO Record (i.e. granted licenses for various uses). Full details of all applications (including those withdrawn and surrendered and those released for commercial use) can be found on the OGTR website at:

<http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/dirclass-2>

Crop	Applicant	Modified Trait	Licence Purpose
Wheat ( <i>Triticum aestivum</i> L.)	CSIRO	Enhanced carbon assimilation, grain weight, heat tolerance and/or water use efficiency, herbicide tolerance	Limited and controlled release of wheat genetically modified for enhanced carbon assimilation in drought and heat prone environments
Wheat and Barley ( <i>Triticum aestivum</i> L. and <i>Hordeum vulgare</i> L.)	CSIRO	Altered grain composition, Nutrient utilisation efficiency	Limited and controlled release of wheat and barley genetically modified for altered grain composition or nutrient utilisation efficiency
Bovine parainfluenza virus (Medi 534)( <i>Bovine parainfluenza virus</i> type 3)	PPD	Attenuation, Foreign antigen expression	Limited and controlled release of a genetically modified vaccine for prevention of selected childhood respiratory diseases
Sugarcane ( <i>Saccharum</i> spp.)	BSES Limited	Herbicide tolerance	Limited and controlled release of sugarcane genetically modified for herbicide tolerance
Sugarcane ( <i>Saccharum</i> spp.)	BSES Limited	Altered plant growth, enhanced drought tolerance, enhanced nitrogen use efficiency, altered sucrose accumulation, and improved cellulosic ethanol production from sugarcane biomass	Limited and controlled release of sugarcane genetically modified for altered plant growth, enhanced drought tolerance, enhanced nitrogen use efficiency, altered sucrose accumulation, and improved cellulosic ethanol production from sugarcane biomass
Wheat and Barley ( <i>Triticum aestivum</i> L. and <i>Hordeum vulgare</i> L.)	CSIRO	Enhanced nutrient utilisation efficiency	Limited and controlled release of wheat and barley genetically modified for enhanced nutrient utilisation efficiency
Wheat and Barley ( <i>Triticum aestivum</i> L. and <i>Hordeum vulgare</i> L.)	CSIRO	Altered grain starch composition	Limited and controlled release of wheat and barley genetically modified for altered grain starch composition
Wheat ( <i>Triticum aestivum</i> L.)	CSIRO	Altered grain composition	Limited and controlled release of wheat genetically modified for altered grain composition
Cotton ( <i>Gossypium hirsutum</i> ) L.	Dow AgroSciences Australia Ltd	Insect Resistance	Commercial release of cotton genetically modified for insect resistance (WideStrike™ Insect Protection Cotton)
Rose ( <i>Rosa X hybrida</i> )	Florigene Pty Ltd	Altered flower colour	Commercial release of rose genetically modified for altered flower colour
White Clover ( <i>Trifolium</i>	Victorian	Viral disease resistance, Antibiotic	Limited and controlled release of white

<i>repens</i> L.)	Department of Primary Industries	resistance	clover genetically modified to resist infection by Alfalfa mosaic virus
Cotton ( <i>Gossypium hirsutum</i> L.)	Bayer CropScience Pty Ltd	Insect resistance, herbicide tolerance	Limited and controlled release of cotton genetically modified for insect resistance and herbicide tolerance
Maize (corn) ( <i>Zea mays</i> L.)	CSIRO	The genetic modification helps to identify maize genes that may alter plant characteristics. Antibiotic resistance, herbicide tolerance and reporter gene activity	Limited and controlled release of maize genetically modified to investigate gene function
Cotton ( <i>Gossypium hirsutum</i> L.)	CSIRO	Fatty acid composition of the cottonseed oil	Limited and controlled release of cotton genetically modified for altered fatty acid composition of the cottonseed oil
Torenia ( <i>Torenia x hybrida</i> )	Florigene Pty Ltd	Phosphate uptake	Limited and controlled release of torenia genetically modified for enhanced phosphate uptake
Cotton ( <i>Gossypium hirsutum</i> L.)	CSIRO	Waterlogging tolerance	Limited and controlled release of cotton genetically modified for enhanced waterlogging tolerance
Perennial ryegrass and tall fescue ( <i>Lolium perenne</i> L.) and ( <i>Lolium arundinaceum</i> ) (Schreb.) Darbysh	Victorian Department of Primary Industries	Altered lignin and fructan metabolism	Limited and controlled release of perennial ryegrass and tall fescue genetically modified for improved forage qualities
Cotton( <i>Gossypium hirsutum</i> L.)	Monsanto Australia Limited	Water use efficiency	Limited and controlled release of cotton genetically modified for enhanced water use efficiency
Bread Wheat( <i>Triticum aestivum</i> L.)	Victorian Department of Primary Industries	Drought tolerance	Limited and controlled release of wheat genetically modified for drought tolerance
Banana( <i>Musa. acuminata</i> cv. Grande Naine)	Queensland University of Technology	Enhanced disease resistance, reporter gene expression	Limited and controlled release of banana genetically modified for disease resistance
Sugarcane ( <i>Saccharum spp.</i> )	The University of Queensland	Altered sugar production	Limited and controlled release of sugarcane genetically modified for altered sugar production
Wheat and barley( <i>Triticum aestivum</i> )and ( <i>Hordeum vulgare</i> )	The University of Adelaide	Enhanced tolerance to abiotic stressors, including soil boron and drought, and increased beta glucan levels	Limited and controlled release of wheat and barley genetically modified for enhanced tolerance to abiotic stresses or increased beta glucan
Banana ( <i>Musa. acuminata</i> cv. Williams)	Queensland University of	Increased levels of pro-vitamin A, vitamin E or iron	Limited and controlled release of banana genetically modified for enhanced

	Technology		nutrition
Cotton ( <i>Gossypium barbadense</i> L.)	Monsanto Australia Limited	Insect resistance and/or herbicide tolerance	Limited and controlled release of GM insect resistant and/or herbicide tolerant <i>Gossypium barbadense</i> cotton
Cotton ( <i>Gossypium hirsutum</i> L.)	Monsanto Australia Limited	Insect resistance and insect resistance/herbicide tolerance	Limited and controlled release of GM insect resistant and insect resistant/herbicide tolerant cotton
Bread wheat ( <i>Triticum aestivum</i> L.)	Department of Primary Industries - Victoria	Drought tolerance	Limited and Controlled Release of GM drought tolerant wheat
Sugarcane ( <i>Saccharum</i> spp.)	BSES Limited	Altered plant architecture, enhanced water or improved nitrogen use efficiency	Limited and Controlled Release of GM Sugarcane with altered plant architecture, enhanced water or improved nitrogen use efficiency
Canola and Indian Mustard ( <i>Brassica napus</i> L. and <i>Brassica juncea</i> L.)	Bayer CropScience Pty Ltd	Herbicide tolerance and hybrid breeding system	Limited and controlled release of GM herbicide tolerant hybrid <i>Brassica napus</i> and hybrid <i>Brassica juncea</i>
Cotton ( <i>Gossypium hirsutum</i> L.)	CSIRO	Waterlogging tolerance	Limited and Controlled Release of Waterlogging Tolerant (GM) Cotton
Cotton ( <i>Gossypium hirsutum</i> L.)	Monsanto Australia Limited	Herbicide tolerant and/or insect resistant	Commercial Release of GM herbicide tolerant and/or insect resistant cotton lines north of latitude 22° South
Cotton ( <i>Gossypium hirsutum</i> L.)	Monsanto Australia Limited	Water-use efficiency	Limited and Controlled Release of Water-Efficient Genetically Modified Cotton
Cotton ( <i>Gossypium hirsutum</i> L.)	Hexima Ltd	Fungal resistance	Field trial of GM cotton expressing natural plant genes for fungal control
Cotton ( <i>Gossypium hirsutum</i> L.)	Bayer CropScience Pty Ltd	Herbicide tolerance	Commercial release of herbicide tolerant Liberty Link® Cotton
Indian mustard (includes Brown and Oriental mustard) ( <i>Brassica juncea</i> L. Czern and Coss.)	Bayer CropScience Pty Ltd	Herbicide tolerance and hybrid breeding system	Field trials of genetically modified herbicide tolerant, hybrid <i>Brassica juncea</i>
Bread wheat ( <i>Triticum aestivum</i> L.)	CSIRO	Altered grain starch and Antibiotic resistance	Field trial of genetically modified wheat with altered grain starch
Sugarcane ( <i>Saccharum officinarum</i> L. x <i>S. spontaneum</i> L.)	The University of Queensland	Altered sugar production and antibiotic resistance	Field trial of genetically modified (GM) sugarcane expressing sucrose isomerase
Bovine herpesvirus 1 (BoHV-1) ( <i>Bovine herpesvirus 1</i> subtype 1.2b)	Queensland Department of Primary	<ul style="list-style-type: none"> <li>• expression of green fluorescent protein (GFP)</li> <li>• expression of envelope</li> </ul>	Vaccination of cattle with recombinant bovine herpesvirus vaccines



strain V155)	Industries & Fisheries	glycoprotein E2 <ul style="list-style-type: none"> <li>• expression of a truncated E0 glycoprotein fused to GFP or to the E2 glycoprotein</li> <li>• localisation of introduced proteins on the surface of the GMOs or host cells</li> <li>• deletion or disruption of endogenous BoHV-1 genes</li> </ul>	
Cotton ( <i>Gossypium hirsutum</i> L.)	Hexima Limited	Insecticidal action, antibiotic resistance	Field trial to assess transgenic cotton expressing natural plant genes for insect control
White Clover ( <i>Trifolium repens</i> L.)	Department of Primary Industries (Victoria)	Viral Disease Resistance, Antibiotic resistance	Field Evaluation of Genetically Modified White Clover Resistant to Infection by Alfalfa Mosaic Virus
Fowl adenovirus (Fowl adenovirus, serotype 8, isolate CFA44)	Imugene Limited	Immunomodulatory protein expression, Attenuation	Limited and controlled release of GM fowl adenovirus (FAV)
Cotton ( <i>Gossypium hirsutum</i> L.)	Dow AgroSciences Australia Pty Ltd	Insecticidal and herbicide tolerance	Agronomic assessment and seed increase of transgenic cottons expressing insecticidal genes (cry1Ac and cry1Fa) from <i>Bacillus thuringiensis</i>
Cotton ( <i>Gossypium hirsutum</i> L.)	Syngenta Seeds Pty Ltd	Insect resistance, antibiotic resistance	The Evaluation of Transgenic Cotton Plants Expressing the VIP Gene
Cholera vaccine ( <i>Vibrio cholerae</i> )	CSL Ltd	Attenuation by removal of cholera toxin subunit A and inclusion of a mercury resistance marker	Commercial release of recombinant live oral cholera vaccine (Orochol® vaccine)
Canola ( <i>Brassica napus</i> L.)	Bayer CropScience Pty Ltd	herbicide tolerant hybrid canola	Field Trial - Seed increase and field evaluation of herbicide tolerant hybrid canola
Grapevines ( <i>Vitis vinifera</i> L.)	CSIRO	Expression of modified colour, sugar composition, flowering and fruit development, expression of green fluorescence protein, antibiotic resistance	Field trial of GM grapevines - Evaluation of berry colour, sugar composition, flower and fruit development and gene flow study
Pineapple ( <i>Ananas comosus</i> )	Department of Primary Industries	Reduction of blackheart, delayed flowering, reporter gene expression, antibiotic resistance	Field trial of pineapple plants modified for blackheart reduction and to delay flowering
Papaya ( <i>Carica papaya</i> )	The University of Queensland	Delayed fruit ripening, reporter gene expression and antibiotic resistance	Field trial for evaluation of GM papaya to delay fruit ripening and to test the expression of the introduced genes
Canola ( <i>Brassica napus</i> L.)	Bayer CropScience Pty Ltd	Herbicide tolerance, Hybrid Breeding System	Commercial release of InVigor® hybrid canola ( <i>Brassica napus</i> ) for use in the Australian cropping system

Canola ( <i>Brassica napus</i> L.)	Monsanto Australia Limited	Herbicide tolerance	General release of Roundup Ready® canola ( <i>Brassica napus</i> ) in Australia
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### APPENDIX III: APPROVED GM FOOD PRODUCTS

The following table contains a current list of approved biotech food products. Detailed information is contained in [Standard 1.5.2](#) on the FSANZ web site.

Food produced using gene technology	Special conditions
Food derived from amylase-modified corn line 3272	
Food derived from glufosinate ammonium-tolerant corn line T25	
Food derived from glufosinate ammonium-tolerant cotton line LL25	
Food derived from glufosinate ammonium-tolerant rice line LLRICE62	
Food derived from glufosinate ammonium-tolerant soybean lines A2704-12 and A5547-127	
Food derived from glyphosate-tolerant corn line GA21	
Food derived from glyphosate-tolerant cotton line GHB614	
Food derived from glyphosate-tolerant corn line NK603	
Food derived from glyphosate-tolerant cotton line MON 88913	
Food derived from glyphosate-tolerant lucerne J101 and J163	
Food derived from glyphosate-tolerant soybean line 40-3-2	
Food derived from glyphosate-tolerant soybean line MON 89788	
Food derived from glyphosate-tolerant sugarbeet line 77	
Food derived from herbicide-tolerant soybean line DP-356043-5	
Food derived from high lysine corn line LY038	Unless the protein content has been removed as part of a refining process, the label on or attached to a package of a food derived from high lysine corn line LY038 must include a statement to the effect that the food has been genetically modified to contain increased levels of lysine.
Food derived from high oleic acid soybean line DP-305423-1	
Food derived from high oleic acid soybean lines G94-1, G94-19 and G168	The label on or attached to a package of a food derived from high oleic acid soy bean lines G94-1, G94-19 and G168 must include a statement to the effect that the food has been genetically modified to contain high levels of oleic acid

Food derived from insect- and potato leafroll virus-protected potato lines RBMT21-129, RBMT21-350, and RBMT22-82.	
Food derived from insect- and potato virus Y-protected potato lines RBMT15-101, SEM15-02 and SEM15-15.	
Food derived from insect-protected and glufosinate-ammonium tolerant corn line 1507	
Food derived from insect-protected and glufosinate ammonium-tolerant DBT418 corn	
Food derived from insect-protected and glyphosate-tolerant corn line MON88017	
Food derived from insect-protected and herbicide-tolerant cotton line T304-40	
Food derived from insect-protected Bt-176 corn.	
Food derived from insect-protected corn line MIR162	
Food derived from insect-protected corn line MIR604	
Food derived from insect-protected corn line MON 810	
Food derived from insect-protected corn event MON863	
Food derived from insect-protected corn line MON 89034	
Food derived from insect-protected cotton line COT67B	
Food derived from insect-protected, glufosinate ammonium-tolerant Bt-11 corn.	
Food derived from insect-protected, glufosinate ammonium-tolerant corn line DAS-59122-7	
Food derived from insect-protected potato lines BT-06, ATBT04-06, ATBT04-31, ATBT04-36, and SPBT02-05	
Food derived from sugar beet line H7-1	
Food derived from bromoxynil-tolerant cotton containing transformation events 10211 and 10222	
Food derived from glyphosate-tolerant cotton line 1445	
Food derived from insect-protected cotton line COT102	
Food derived from insect-protected cotton lines containing event 15985	
Food derived from insect-protected cotton lines 531, 757 and 1076	
Food derived from insect-protected, glufosinate ammonium-tolerant cotton line MXB-13	

Oil derived from bromoxynil-tolerant canola line Westar-Oxy-235	
Oil derived from glufosinate-ammonium tolerant canola lines Topas 19/2 and T45 and glufosinate-ammonium tolerant and pollination controlled canola lines Ms1, Ms8, Rf1, Rf2 and Rf3	
Oil derived from glyphosate-tolerant canola line GT73	